CLIAC Recommendations for Laboratory Interoperability

DATE RECOMMENDED	CATEGORY	CLIAC RECOMMENDATION	STATUS
February 9-10, 2010	Miscellaneous	Create an electronic healthcare record (EHR) workgroup tasked with writing a work statement that includes specific issues and recommendations for stakeholders to address. The Committee requested updates regarding the progress of the identified issues in future meetings.	The Communication in Informatics workgroup met in July 11-12, 2012. Updates on EHR implementation have been given at CLIAC meetings since 2011.
August 31-September 1, 2011	Miscellaneous	Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.	The Communication in Informatics workgroup met July 11-12, 2012 and reported to CLIAC in August 29, 2012. Communication issues, in general, continue to be an ongoing topic of CLIAC discussions.

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August 29-30, 2012	Electronic Health Record (EHR)	CLIAC recognizes that serious patient safety risks can arise from errors in the order entry, transmission, display and interpretation of laboratory data in EHRs. Display and use of non-numerical laboratory information is an under-appreciated critical issue. Interoperability with LIS as well as correct transmission of data across multiple interfaces is also critical. The laboratory community can provide important input and solutions to these challenging problems. CLIAC makes the following recommendations: 1. Laboratory experts with experience in hospital, ambulatory or public health settings should be members of key ONC advisory committees and other agency groups that are setting standards and policies for laboratory information in EHRs. 2. Provider usability is an important strategy for mitigation of these patient safety risks. Further work in this area should be supported. 3. A national system for reporting EHR laboratory related safety events and near misses should be established to clearly define the prevalence, understand the underlying causes and stimulate the design of broad-based solutions. 4. A catalogue of various solutions for laboratory data should be created using work that has already been done and considering areas of expertise [e.g., human factors] that may not have been previously engaged.	CLIAC sent a letter (dated September 26, 2012) to the Secretary, HHS, that included this recommendation. HHS reported to CLIAC on steps being taken in response to the recommendation on August 22, 2013. The letter can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Aug_2012_HHS_EHR.pdf.
April 15-16, 2015	Electronic Health Record (EHR)	HHS should convene a multidisciplinary stakeholder group that: • Includes, but is not limited to, representatives from ONC, CMS, FDA, CDC, industry representatives, health IT developers/vendors, all CLIA approved accrediting organizations, informaticians, lab directors/professionals, provider end-users, patient/consumer representatives, & other relevant professional organizations • Proposes a framework for achieving safe & effective lab interoperability (both system and patient facing) that encourages innovation and defines how to operationalize interoperability (and related deliverables) with detailed use cases • Provides both short term next steps and long term goals with definable measurable actions and outline who is responsible for these actions • Puts into place robust measurement and evaluation strategies for goal achievement.	CLIAC sent a letter (dated May 6, 2015) to the Secretary, HHS, that included this recommendation. HHS response was sent on July 24, 2015. CLIAC was provided the HHS letter and response on November 5, 2015. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2015_HHS_Interoperability.pdf.

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November 18-19, 2015	Electronic Health Record (EHR)	HHS should ensure the following next steps: • EHR content display related to laboratory data (including graphs) should be standardized such that all CLIA-required test report elements are on every laboratory display/graph. • National Institute of Standards and Technology (NIST) should create use cases for testing transmission and display of laboratory data in the pre- and post-implementation stages of EHR use in order to maintain semantic interoperability in various laboratory (clinical/anatomic pathology) settings. Use cases should start at the laboratory system and involve sending data across the interface for display in multiple EHRs. This would test the interoperability of comments, units, reference ranges, etc. (sometimes the reference ranges in the EHR are different than in the laboratory information system). • Consider the incorporation of CLIA use cases in next certification cycle. • The Centers for Medicare & Medicaid Services (CMS) should consider identifying activities considered as 'information blocking' and place multifaceted strategies to discourage such activities. For example, incentives could be built for offsetting the current high fees for laboratory/EHR interfaces.	CLIAC sent a letter (dated January 4, 2016) to the Secretary, HHS, that included this recommendation. HHS response was sent on March 7, 2016. CLIAC was provided the HHS letter and response on April 13, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov_2015_HHS_Interoperability.pdf.
April 13-14, 2016	Laboratory Interoperability	To facilitate wider uptake of standards for laboratory interoperability, HHS should endorse and stimulate adoption of an implementation guide/s for laboratory results reporting (e.g., The EHR-Lab Interoperability and Connectivity Specification (ELINCS) for orders available at: http://www.chcf.org/projects/2009/elincs); and successful pilots that arise from the S&I framework effort (http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative)	CLIAC sent a letter (dated May 9, 2016) to the Secretary, HHS, that included this recommendation. HHS response was sent on June 15, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2016_HHS_Interoperability.pdf.

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April 13-14, 2016	Laboratory Interoperability	CLIAC requests that the Office of the National Coordinator for Health Information Technology (ONC) Standards and Policy Committees each include a pathology informatician (pathologist with expertise in clinical informatics) as a committee member.	CLIAC sent a letter (dated May 9, 2016) to the Secretary, The U.S. Department of Health and Human Services (HHS), that included this recommendation. HHS response was sent on June 15, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2016_HHS_Interoperability.pdf.

November 1-2, 2017	Laboratory Interoperability	Pathologist as an Integral Team Member
		HHS should encourage the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error.
		• Areas of special interest could include consultations by laboratory professionals e.g. pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients.
		• Evaluation should include patient and provider outcomes (including satisfaction), and health system outcomes (e.g. costs) including innovation's implementation related challenges and opportunities.
		
		Interoperability
		CLIAC recommends that HHS create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity) to:
		1. Better understand the nuances, specificity, and compatibility of sharing LOINC or other standard codes,
		  a. on both order-and result-side implementation, and
		  b. in special cases (radiology, clinical findings, anatomic pathology, molecular diagnostics, etc.).
		2. Identify areas in which a combination(s) of standards is needed to realize the level of granularity and semantic interoperability necessary to achieve the IOM goals.
			CLIAC sent a letter (dated February 6, 2018) to the Secretary of the U.S. Department of Health and Human Services (HHS) that included this recommendation. The letter can be found at https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov2017_HHSLetter_Interoperability.pdf.